

### **Remarks**

The pending final Office Action addresses and rejects claims 1-6, 11-13, 15 and 24. Applicant responds to the final Office Action and submits herewith a Request for Continued Examination.

Applicant requests reconsideration of the present application in view of the amendments herein. Claims 1, 2-6, 11-13, 15, 24, 37-40 are pending in the above-referenced application. Applicant has amended claims 1, 2-6, 11-13, 15 and 24 herein, and cancelled claims 7-10, 14, 16-23, and 25-36. Applicant has also added claims 37-40.

At the outset, applicant thanks the Examiner for extending the courtesy of an interview to applicant's undersigned representative on March 21, 2007. In the interview, the Examiner and applicant discussed the issues raised by the final Office Action. In particular, applicant proposed amending independent claims 1 and 24 to include "a support" "having at least one *outlet* on a surface of the support." Although no agreement was reached during the interview, the Examiner invited applicant to submit applicant's proposed amendments with arguments so that the Examiner could further consider applicant's claims. Accordingly, applicant submits herein applicant's amended claims and remarks.

### **Amendments to the Claims**

Applicant has cancelled previously withdrawn claims 7-10, 1, 16-23, and 25-36 without prejudice, reserving the right to pursue these claims in a divisional application.

Applicant has amended independent claims 1 and 24 to remove "means" language from claim 1 and replace "supporting means" with "a support." Support for these amendments is found in the specification at, for example, page 3, lines 9-10.

Applicant has also amended independent claims 1 and 24 to recite a support having at least one outlet on a surface of the support. Support for these amendments is found in the specification at, for example, element 54 of Figs. 1A, 1D, 1E, 2A, 2B, 5C and 5D. See also, page 7, lines 6-9.

Newly added dependent claim 37 recites a support that is semi-permeable. Support for this claim is found in the specification at, for example, page 10, lines 16-19.

Newly added dependent claim 38 recites a support that is biodegradable. Support for this claim is found in the specification at, for example, page 10, lines 19-22.

Newly added claims 39 and 40 recite an intervertebral fusion device having an expandable balloon and the materials from which the balloon is made. Support for these claims is found in the specification at, for example, page 10, lines 14-24.

### ***Claim Rejections Pursuant to 35 U.S.C. § 103***

#### **Claims 1-6 and 15**

The final Office Action addresses and rejects claims 1-6 and 15 under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 6,375,655 of Zdeblick et al (“Zdeblick”) in view of U.S. Patent No. 6,752,809 of Gorek (“Gorek”). The Examiner admits that Zdeblick does not teach a body with “a conduit throughout” the body as is required by applicant’s independent claim 1. Thus, the Examiner relies on Gorek to remedy this deficiency. In particular, the Examiner relies on Gorek to teach “a conduit throughout allowing access to the vertebral support from the proximal end,” arguing that “it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Zdeblick “having at least a conduit throughout in view of Gorek to better have access to the vertebral portion.” Applicant respectfully disagrees.

It would not be obvious to a person of ordinary skill in the art to modify the inter-body fusion device of Zdeblick with Gorek because Gorek is merely a delivery device and does not even relate to intervertebral support devices. Gorek just discloses a bone cement injector system, which is no more combinable with an intervertebral support device than a syringe would be.

Applicant submits that the Examiner fails to apply the legal requirement that the prior art be shown to provide sufficient motivation to one of ordinary skill in the art to combine Zdeblick with Gorek. In combining references in an obviousness rejection, an examiner may not simply pick and choose elements from different references, but must identify a teaching or motivation to combine the elements. The Federal Circuit has stated:

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing “teaching or suggestion or motivation [to combine]” as an “essential evidentiary component of an obviousness holding”); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) (“the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them”); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination “only by showing some objective teaching [leading to the combination]”); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion “essential” to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court’s conclusion of obviousness was error when it “did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination”). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 (“strict observance” of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) (“The invention must be viewed not with the blueprint drawn drawn by the inventor, but in the state of the art that existed at the time.”).

*In re Dembiczak*, 50 USPQ 1614 (Fed. Cir. April 28, 1999).

Accordingly, Applicant submits that Zdeblick and Gorek are improperly combined because the Examiner has not provided clear and particular reasons for combining Zdeblick’s interbody fusion device with Gorek’s bone cement injector system since Gorek does not even relate to an intervertebral support device.

Furthermore, applicant respectfully submits that in combining Zdeblick with Gorek, the Examiner has mistakenly concluded that Zdeblick teaches a conduit in a body which is in fluid

communication with a conduit in a support as is recited in applicant's claim 1. The Examiner states "the open inside of the supporting means is considered in fluid communication with the **conduit** of the body." Applicant respectfully submits that Zdeblick's implant driver lacks any type of a conduit. Rather, Zdeblick's implant driver merely has "slot" which supports a pair of tongs for **gripping** an interbody fusion device. This slot is in no way able to communicate fluidly with the fusion device. (See Zdeblick for example, at column 9, lines 42-56.)

Applicant further submits that claims 1-6 and 15 are allowable since neither Zdeblick nor Gorek, alone or in combination, teach or suggest at least one outlet on the surface of a support as recited in applicant's amended claim 1.

Therefore, Applicant respectfully requests that the Examiner withdraw rejection of claims 1-6 and 15 since Zdeblick and Gorek fail to teach or suggest applicant's invention, alone or in combination.

In view of all of the above enumerated deficiencies in Zdeblick and Gorek, and further in view of Applicant's discussion of the novel features of claims 1-6 and 15 as amended herein, applicant respectfully submits that the Examiner's rejection be withdrawn and pending claims 1-6, and 15 be allowed.

#### **Claims 11-13 and 24**

The final Office Action also addresses and rejects claims 11-13 and 24 under 35 U.S.C. § 103 as being obvious over Zdeblick and Gorek in view of U.S. Pub 2003/0028251 of Mathews. The Examiner argues that the combination of Zdeblick and Gorek disclose the claimed invention "except for a supporting means that is a balloon that and materials, used in the supporting implant or in the balloon may facilitate bone growth, or a flowable material (sic)." The Examiner relies on Mathews to remedy these deficiencies, alleging that Mathews teaches a spinal device that is capable of being a support device as a balloon that is capable of providing support and that may be made of bioreactive, or bioresorbable material and that is flowable. Applicant respectfully disagrees.

First, applicant respectfully submits that claims 11-13 are allowable for the same reasons that claim 1 is allowable, as set forth above, since claims 11-13 depend from independent claim 1 and include all of the limitations of claim 1.

Furthermore, Mathews does not remedy the deficiencies of Zdeblick and Gorek with respect to applicant's claims 11-13 and 24 because Mathews does not teach a support having an outlet, as recited in applicant's amended claims 1 and 24. Furthermore, Mathews does not disclose a balloon which is resorbable but merely says that the material which fills the balloon can be resorbable.

Accordingly, applicant respectfully requests that the Examiner withdraw the rejection of claims 11-13 and 24 in view of the arguments above and in view of applicant's amendments of claims 1 and 24 herein.

**Conclusion**

In view of the foregoing, applicant respectfully requests that the Examiner allow claims 1-6, 11-13, 15, 24, and 37-40.

Respectfully submitted,

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